PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY NOTIFICATION OF TRANSMITTAL OF CARPMAELS & RANSFORD THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL Attn. Tunstall, Christopher S SEARCHING AUTHORITY, OR THE DECLARATION 43-45 Bloomsbury Square London WC1A 2RA 0 1 OCT 2009 GRANDE BRETAGNE CARPINAELS & RANSFORI ACTIONED (PCT Rule 44.1) Date of mailing (day/month/year) 30/09/2009 Applicant's or agent's file reference FOR FURTHER ACTION See paragraphs 1 and 4 below P050902WO International filing date International application No. (day/month/year) 10/06/2009 PCT/GB2009/001447 Applicant CILAG GMBH INTERNATIONAL The applicant is hereby notified that the international search report and the written opinion of the international Searching 1. x Authority have been established and are transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international Application (see Rule 46): When? The time limit for filing such amendments is normally two months from the date of transmittal of the international Search Report. Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70 For more detailed instructions, see the notes on the accompanying sheet. 2. The applicant is hereby notified that no International search report will be established and that the declaration under Article 17/2/(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

Reminders

Reminders

Shortly after the expiration of 18 months from the priority date, the international spirication will be published by the international spirication will be spiricative which be bond of odespone, published, an oblige of which should be international spirications, an oblige of which should be international surround by the control of the spiritude of the technical preparations for international surround surround the spiritude of the technical preparations for international surround so that the spiritude of the spiritude of the technical preparations for international publication.

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made vet on the protest; the applicant will be notified as soon as a decision is made.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the international Bursus. The International Bursus with send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the excitation of 30 months from the priority date.

Within 18 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination mask be tiled the applicant wisers to protope the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry in the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentiaan 2

NL-2280 HV Rijswijk

El.i

El.i

Elisabetta Sulis

Authorized officer

Fax: (+31-70) 340-3016

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filling of amendments under article 19. The Notes are based on the requirements of the Patient Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty, in case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see size the *PCT Applicant's Quide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It is hould however be emphasized that, since all parts of the international application (radians,description and drawings) may be amended during the international perintimary examination procedure, there is usually no need to the amendment of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has softwise.

The provisional procedure is the provisional procedure is the provisional protection or the softwise procedure in the provisional protection is available in some States only (see PCT Accidents's Guide's Volume IVA, Amorea St 1 and IS21.

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the international Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the International phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the International search report or 16 months from the priority date, whichever time limit expires latel, it should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Pulse 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filled and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several daims may be grouped),whether.

- (i) the claim is unchanged;
- (ii) the claim is cancelled:
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]: "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 39, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11.
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims!
 - "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 18 replaced by amended claim 14, claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added.

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

it must be brief, not exceeding 500 words If in English or If translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of tiling any amendments and any accompanying statement, under Article 19, a demand for international performancy examination has already been submitted, the applicant must preferably, at the time of tiling the amendments (and any statement) with the international Bureau, also file with the international Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentency). For turner information, some the Notes to the demand form (CPT/TMEPA401).

It a demand for international prailminary examination is made, the written opinion of the international Searching Authority will, except in contain cases where the international Preliminary Examining Authority did not act as international Searching Authority and where it has notified the international Searching Authority and where it has notified the international Searching Authority, and describe the source of the international Preliminary Examining Authority, it and demand is made applicant may submit to the international Preliminary Examining Authority, and demand is made applicant may submit the international Preliminary Examining Authority. It as demand is made applicant may submit the international Preliminary Examining Authority and Research applications of Samonthis from the date of mailing of Form Prof. ISIASZCO to before the experiment of 22 months from the profit of side, whichever express state (Fulle 495ts. 1(d.)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designatedelected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the PCT Applicant's Guide,

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER	see Form PCT/ISA/220				
P050902WO	ACTION	as well as, where applicable, Item 5 below.				
International application No.	International filing date (day/month/year) (Earliest) Priority Date (day/month/					
PCT/GB2009/001447	10/06/2009	19/06/2008				
Applicant						
CILAG GMBH INTERNATIONAL						
This international enough report has been	prepared by this interestional Contra	ing Authority and is transmitted to the applican				
according to Article 18. A copy is being to	ansmitted to the International Bureau	ing Additionty and is transmitted to the applican	ı			
This international search report consists of	of a total of5shee	s.				
X It is also accompanied by	a copy of each prior art document of	ed in this report.				
1 Basis of the report						
a. With regard to the language, the	international search was carried out	n the basis of:				
X the international a	application in the language in which i	was filed				
a translation of the	e international application into rnished for the purposes of internation	, which is the language nal search (Rules 12.3(a) and 23.1(b))				
b. This International search	report has been established taking in	o account the rectification of an obvious mis	take			
_	this Authority under Rule 91 (Rule					
c. With regard to any nuclei	otide and/or amino acid sequence	lisclosed in the international application, see Bo	X No. I.			
2. Certain claims were fou	nd unsearchable (See Box No. II)					
3. Unity of invention is lac	king (see Box No III)					
4. With regard to the title,						
the text is approved as su	ibmitted by the applicant					
X the text has been establis	shed by this Authority to read as folio	s:				
AUTOMATIC INJECTION DE	EVICE WITH TRIGGER LOC					
		· .				
With regard to the abstract,						
the text is approved as su	ubmitted by the applicant					
X the text has been establis may, within one month from	shed, according to Rule 38.2(b), by the om the date of mailing of this internal	s Authority as it appears in Box No. IV. The app anal search report, submit comments to this Aut	licant hority			
6. With regard to the drawings,						
a. the figure of the drawings to be published with the abstract is Figure No. 1						
X as suggested by						
=	is Authority, because the applicant fa	ed to suggest a figure				
=	is Authority, because this figure bette					
b. none of the figures is to b	e published with the abstract					
Form PCT/ISA/210 (first sheet) (April 2007)						

International application No.

PCT/GB2009/001447

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An injection device comprises a housing adapted to receive a syringe having a discharge nozzle, the syringe being moveable in the housing on actuation of the injection device along a longitudinal axis from a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle of the syringe extends from the housing through an exit aperture (138). There is an actuator and a drive adapted to be acted upon by the actuator and in turn act upon the syringe to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle. A locking mechanism (119) is moveable from an engaged position in a direction into the housing at the exit aperture into a disengaged position. The locking mechanism is adapted to prevent actuation of the device when it is in its engaged position and permit actuation of the device when it is in its disengaged position. The exit aperture is defined by a rim (128a) located on an edge of the housing and the locking mechanism comprises a contact surface (119a) which is adapted to extend over or around at least a part of the rim.

International application No PCT/GB2009/001447

Relevant to claim No.

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/20

C. DOCUMENTS CONSIDERED TO BE RELEVANT

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Citation of document, with indication, where appropriate, of the relevant passages

EPO-Internal

Category*

x 🗸	US 2003/105430 A1 (LAVI GILAD [U: GIL [US]; TSALS IZRAIL [US]) 5 June 2003 (2003-06-05)	1-14, 22-23				
Y	paragraph [0187] - paragraph [019 figures 37-47	15-21				
x ✓	WO 2007/051330 A1 (TECPHARMA LIC [CH]; HOMMANN EDGAR [CH]) 10 May 2007 (2007-05-10)	1-14, 22-23				
Y	page 9, paragraph 3 - page 15, p. 2; figures 1-7	15-21				
x ✓	US 2006/270986 A1 (HOMMANN EDGAR SCHERER BENJAMIN [CH]) 30 November 2006 (2006-11-30)	1-14, 22-23				
Υ	paragraph [0043]; figures 1A-3		15-21			
		-/	*			
*						
X Furth	er documents are listed in the continuation of Box C.	X See patent family annex.				
"A" docume consid "E" earlier of filing d	Special categories of clad documents: **To **Document departies of the act which is not considered to be of prefer the application by the applica					
'O' docume other i	n or other special reason (as specified) ent referring to an oral disclosure, use, exhibition or	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art." The document is not existed to the such as the set. "S" document member of the same patent family				
Date of the	Date of the actual completion of the international search Date of mailing of the international search					
2	22 September 2009 30/09/2009					
Name and r	Name and mailing address of the ISA/ Interpretable Total Patients Name and mailing address of the ISA/ Interpretable Total Patients Total (-91-70) 340-2000. B 1örk lund. Andreas					

Fax: (+31-70) 340-3016

2

International application No PCT/GB2009/001447

ategory*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
	WO 2007/036676 A1 (CILAG GMBH INT [CH]; HABESHAW ROSIE LOUISE [GB]; JOHNSTON DAVID MAXWEL) 5 April 2007 (2007-04-05) cited in the application	1-14, 22-23		
'	page 8, line 8 - page 9, line 28; figures 1-8	15-21		
: 1	WO 2006/106294 A1 (CILAG AG INT [CH]; JENNINGS DOUGLAS IVAN [GB]; DEAN CHARLES	1-14, 22-23 15-21		
	MICHAEL [U) 12 October 2006 (2006-10-12) page 4, line 25 - page 5, line 18; figures 1-4			
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		8		

Information on patent family members

International application No PCT/GB2009/001447

						,	,
	tent document in search report		Publication date		Patent family member(s)	*	Publication date
UŞ	2003105430	- A1	05-06-2003	WO	03047663	A2	12-06-2003
WO	2007051330	A1	10-05-2007	AU	2006310971		10-05-2007
				CN	101355977		28-01-2009
				DE	102005052502		16-05-2007
				EP	1945286		23-07-2008
				JP	2009514572		09-04-2009
				US	2008262427	A1	23-10-2008
US	2006270986	A1	30-11-2006	WO	2005044347	A1	19-05-2005
				DE	10351598		16-06-2005
				JP	2007509659	T	19-04-2007
WO	2007036676	A1	05-04-2007	AU	2005336826	A1	05-04-2007
				BR	PI0520572	A2	19-05-2009
				CA	2623962	A1	05-04-2007
				CN	101346157		14-01-2009
				EA	200800939	A1	29-08-2008
				EP	1928523		11-06-2008
				JP	2009509605	T	12-03-2009
WO	2006106294	A1	12-10-2006	AU	2006231103	A1	12-10-2006
				BR	PI0610692	A2	16-06-2009
				CA	2603933		12-10-2006
				CN	101262898		10-09-2008
				EΑ	200701960		28-02-2008
				EP	1890746		27-02-2008
				GB	2427826		10-01-2007
				JP	2008534206		28-08-2008
				KR	20080040621		08-05-2008
				ZA	200709517	Α	25-02-2009

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING ALITHORITY PCT To: WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/GR2009/001447 10.06.2009 19.06.2008 International Patent Classification (IPC) or both national classification and IPC INV. A61M5/20 Applicant CILAG GMBH INTERNATIONAL This opinion contains indications relating to the following items: Box No. I Basis of the opinion ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application FURTHER ACTION If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date. whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220 Name and mailing address of the ISA: Date of completion of Authorized Officer this opinion

see form

PCT//SA/210

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2009/001447

_							
_	Вс	x N	o. I Basis of the opinion				
1.	. With regard to the language, this opinion has been established on the basis of:						
	×	th	e international application in the language in which it was filed				
			translation of the international application into , which is the language of a translation furnished for the proses of international search (Rules 12.3(a) and 23.1 (b)).				
2.		Th by	iis opinion has been established taking into account the rectification of an obvious mistake authorized or notified to this Authority under Rule 91 (Rule 43bis.1(a))				
3.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:						
	a.	type	of material:				
			a sequence listing				
			table(s) related to the sequence listing				
	b.	form	nat of material:				
			on paper				
			in electronic form				
	c. time of filing/furnishing:						
			contained in the international application as filed.				
			filed together with the international application in electronic form.				
			furnished subsequently to this Authority for the purposes of search.				
4.		ha	addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto is been filed or furnished, the required statements that the information in the subsequent or additional pies is identical to that in the application as filed or does not go beyond the application as filed, as proportate, were furnished.				
5.	Ad	ditio	nal comments:				

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 6-7, 15-21

No: Claims 1-5, 8-14, 22-23

Inventive step (IS) Yes: Claims

No: Claims <u>1-23</u>

Industrial applicability (IA) Yes: Claims 1-23

No: Claims

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1. Reference is made to the following documents:
- D1 · US 2003/105430 A1 (LAVI GILAD [US]; YIGAL GIL [US]; TSALS IZRAIL [US]) 5 June 2003 (2003-06-05)
- D2 WO 2007/051330 A1 (TECPHARMA LICENSING AG [CH]; HOMMANN EDGAR [CH]) 10 May 2007 (2007-05-10)
- D3 US 2006/270986 A1 (HOMMANN EDGAR [CH]; SCHERER BENJAMIN [CH]) 30 November 2006 (2006-11-30)
- D4 WO 2007/036676 A1 (CILAG GMBH INT [CH]; HABESHAW ROSIE LOUISE [GB]; JOHNSTON DAVID MAXWEL) 5 April 2007 (2007-04-05) cited in the application
- D5 WO 2006/106294 A1 (CILAG AG INT [CH]; JENNINGS DOUGLAS IVAN [GB]; DEAN CHARLES MICHAEL [U) 12 October 2006 (2006-10-12)
- The present application does not meet the criteria of Article 33(1) PCT, because the subject - matter of claims 1-5, 8-14 and 22-23 is not new in the sense of Article 33(2) PCT.
- 2.1. The document D1 discloses (the references in parentheses applying to this document):

An injection device (figs. 37-47) comprising:

a housing (304) adapted to receive a syringe having a discharge nozzle, the syringe being moveable in the housing on actuation of the injection device along a longitudinal axis from a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle of the syringe extends from the housing through an exit aperture;

an actuator (24):

a drive (20, 208, 232) adapted to be acted upon by the actuator and in turn act upon the syringe to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle;

a locking mechanism moveable from an engaged position in a direction into the housing at the exit aperture into a disengaged position (302, 312), wherein the locking mechanism is adapted to prevent actuation of the device when it is in its engaged position and permit actuation of the device when it is in its disengaged position ([0187]-[0188]).

wherein the exit aperture is defined by a rim located on an edge of the housing, and wherein the locking mechanism comprises a contact surface which is adapted to extend over or around at least a part of the rim (seen on fig. 38).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

- 2.2. Also the documents D2-D3 (see references in search report) disclose the subject-matter of claim 1 (Article 33(2) PCT).
- 2.3. Furthermore, the only difference between the subject-matter of claim 1 and the injection devices disclosed in D4-D5 (see references in search report) is the contact surface which is adapted to extend over or around at least part of the rim. This difference does as such not solve any technical problem and is therefore regarded as a non-inventive design option (Article 33(3) PCT). Furthermore, locking mechanisms with contact surfaces extending over or around the rim of exit apertures are known from D1-D3.
- 3. Dependent claims 2-23 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since they merely define trivial design options for injection devices with different locking mechanisms which are known in the art, see documents D1-D5 and the corresponding passages cited in the search report.
- 3.1. In view of the fact that D4 (see references in search report) discloses an injection device which is almost identical to the device of the application, except for the shape of the contact surface. Since locking mechanisms with contact surfaces extending over or around the rim of exit apertures, the application as a whole does not seem to contain any matter which could fulfil the requirements of Article 33(2)-(3) PCT.
- Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).
- 5. Documents D1-D3 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

under Art 19 PCT

Amending claims Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCD). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

Filing informal comments.

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).

Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003